REMARKS

Claims 3-30 are pending in the present application. Claims 12-14 are withdrawn from consideration.

Support for the amendment to claims 15 and 16 can be found in paragraph [0114] of the present specification.

Claim 17 has been amended to remove a typographical error.

Support for new claims 23-28 can be found in claims 17-22, respectively.

Support for new claims 29-30 can be found in claims 18 and 21, respectively.

No new matter has been added by way of the above-amendment.

The following sections correspond to the sections of the outstanding Office Action.

Restriction

Applicants note with appreciation that the Examiner has modified the Restriction Requirement and has rejoined Group IV with elected Group I. Accordingly, the Examiner has examined all of claims 1-11 and 15-22.

Claim Rejections under 35 U.S.C. 112

Claims 17-22 are rejected under 35 U.S.C. 112, 1st paragraph for lacking enablement. Applicants respectfully traverse the rejection.

Specifically, the Examiner has indicated that the experimental evidence in the present specification enables the skilled artisan to use the invention to the extent that the compounds are used in treating depression and anxiety. However, the Examiner does not find that the present specification enables the skilled artisan to use the compounds of the present invention to treat other diseases or for the ***prevention*** of any disease (including depression and anxiety).

Applicants respectfully submit that the Examiner has not set forth a *prima facie* case of non-enablement for claims 17-22, as currently amended. Applicants respectfully submit that the specification contains sufficient guidance to the skilled artisan how to both make and use the claimed invention as discussed in MPEP 2164.01.

MPEP 2164.01 states that:

> "The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. (Citation omitted). The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue." (Citation omitted).

In the outstanding Office Action, the Examiner correctly acknowledges that the test for enablement takes into consideration the *Wands* factors (which will not be repeated verbatim herein) as set forth in MPEP 2164.01(a). However, it is Applicants' contention that the Examiner has not correctly weighed the factors, especially, the factor relating to the state of the prior art.

The Examiner's comments make it clear that the Examiner agrees with Applicants that the inventive compounds are active antagonists for CRF and that the inventive compounds are useful in treating depression and anxiety. There are CRFR binding experiments described in the experimental section of the specification beginning on page 233, which show that the inventive compounds bind to CRFR1. Also, the test example 2 shows that the inventive compounds inhibit the production of cAMP in AtT-20 mouse cell lines derived from mouse pituitary gland tumors.

The Examiner and Applicants disagree that such experiments are sufficient to enable the skilled artisan to make and/or use the inventive compounds to treat or prevent all of the diseases associated with CRF as described in claim 20 or the specific diseases described in claims 21 and 22. Applicants contend that these experiments are sufficient to enable the skilled artisan, since the test for enablement is viewed as of the filing date of the instant invention (MPEP 2164.05(a)), and as such, the Examiner must consider the teachings in the field of the invention prior to the filing date.

The Examiner's attention is directed to the description in the "Background of the Invention" section of the present specification which shows that extensive research has been focused on the activity CRF antagonists in the treatment and prevention of diseases. The following Table shows the specific diseases which are described in the prior art as being treatable/preventable using a CRF antagonist and the specific reference(s) showing the nexus between CRF antagonist activity and efficacy in treatment/prevention.

TABLE

Disease	Reference Showing Nexus
mania	10
panic disorder	2, 8, 10, 11
phobia,	8, 10, 11
obsessive-compulsive disorder	1, 8, 10, 11
posttraumatic stress disorder	1, 8, 9, 10, 11
Tourette's syndrome	1, 10
autism,	10
affective disorder	8, 9
dysthymia,	8, 11
bipolar disorder	8, 10, 11
cyclothymic personality	8, 10, 11
schizophrenia	3, 10
peptic ulcer	4, 5, 8, 9, 10, 11
irritable bowel syndrome	7, 8, 9, 10, 11
ulcerative colitis	9, 10
Crohn's disease	8, 10, 11
diarrhea	7, 8, 9, 10, 11
constipation,	6, 9
postoperative ileus	10
stress-associated gastrointestinal disorder	6, 8, 9, 10, 11
nervous vomiting	11

1) Journal of Endocrinology, 160, 1 (1999)
2) Exp. Clin. Endcrinol. Diabetes, 105, 65 (1997)
3) Am. J. Psychiatry, 144(7), 873 (1987)
4) Am. J. Physiol., 258, G152 (1990)
5) Life Sci., 45, 907 (1989)
6) Gastroenterology, 95, 1510 (1988)
7) Gut, 42, 845 (1998)
8) WO 0059908 and WO 0059907
9) WO0206286
10) WO02062800
11) EP0812831

The Examiner will note that all of the diseases described in claims 21 and 22 are listed in this table.

As such, the prior art has reached a level where there is enough information so that the skilled artisan would not require undue experimentation to make the inventive compounds and use them to treat/prevent the diseases associated with CRF as described in claim 20 or the specific diseases described in claims 21 and 22.

Furthermore, MPEP 2164.04 states that a: "specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C.112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." Applicants believe that the teachings in the specification of the manner and process of making and using the invention are in scope with the invention as claimed when considering the state of the art, and that the Examiner has not provided sufficient reason to doubt the objective truth of the statements contained in the specification. As such, the specification provides an enabling support of the claimed invention and withdrawal of the rejection is respectfully requested.

With respect to new claims 23-28, the Examiner will note that new claims 23-28 do not recite the "prophylactic" use of the compounds and are directed towards the therapeutic use of the compounds. Furthermore, new claims 29-30 are drawn to the treatment of depression and anxiety.

Duplicate Claims

The Examiner objects to claims 15 and 16 under 37 C.F.R. 1.75 for being substantial duplicates of claim 3. In response, Applicants have amended claims 15 and 16 to recite that the

antagonist comprises a pharmaceutically acceptable carrier. Support for this amendment can be found in paragraph [0114] of the present specification. As such, withdrawal of the objection is respectfully requested.

Allowable Subject Matter

Applicants note with appreciation that the Examiner has indicated that claims 3-11 are allowed.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Garth M. Dahlen, Ph.D., Esq. (Reg. No. 43,575) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

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Respectfully submitted,

By Garth M. Dahlen #43575 for
Marc S. Weiner
Registration No.: 32,181
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road
Suite 100 East
P.O. Box 747
Falls Church, Virginia 22040-0747
(703) 205-8000
Attorney for Applicant